IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
WESTERN DIVISION

In re:

Heparin Products Liability Litigation — MDL No. 1953

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Charlisa Allen, etc.,

Plaintiffs, — Case No. 1:10HC60098

v. — **ORDER**

American Capital Ltd., et al.,

Defendants.

This suit, which the Judicial Panel on Multi-District Litigation referred to me, arises from the alleged administration of contaminated heparin to plaintiff's late husband, Dr. Robert Allen (Allen).[1]

Plaintiff asserts six causes of action: 1) strict liability/manufacturing defect; 2) negligence; 3) breach of implied warranty; 4) breach of express warranty; 5) statutory wrongful death; and 6) statutory survival.

Jurisdiction is proper under 28 U.S.C. § 1332.

Pending is defendants' motion for summary judgment. (Docs. 40, 41). For the reasons discussed below, I deny the motion.

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[1] Heparin is an anti-coagulation medication that is designed to prevent the formation of blood clots, or to stop the growth of existing clots. (Doc. 1 ¶ 14). For a more detailed explanation of heparin and the events that led to the MDL, see *In re Heparin Prods. Liab. Litig.*, 803 F. Supp. 2d 712, 720-23 (N.D. Ohio 2011).

Background

On December 1, 2007, at age forty-five, Allen presented to the Scottsdale, Arizona branch of the Mayo Clinic (Mayo) complaining of intermittent abdominal pain over a period of several weeks. (Doc 46-1 at 2).

Because of Allen's prior history of heart problems,[2] doctors ordered an electrocardiogram, which revealed "significant abnormality." (Doc. 461 at 2). The cardiology department recommended Allen's admission and that he have an echocardiogram in the morning as well as a "rule out" protocol. (Doc. 41-1 at 2). He spent the night on the cardiac telemetry floor so that he received "continuous telemetry monitoring." (Doc. 46-18 at 13:25-14:1, 57:1-6, 59:9-12, 62:24-64:23).

An admission document time-stamped at 2:31 a.m. on December 2, 2007 indicates that Allen was admitted in "stable" condition. (Doc. 46-10 at 3). It also states his anticipated length of stay was one to two days. (*Id.*).

Allen received his first dose of heparin (5000-units/ML, 1 ML vial) at approximately 6:00 a.m. About three hours after the first heparin administration, at 8:50 a.m., Allen's cardiac enzyme (troponin) became modestly elevated. (Doc. 46-1 at 2; Doc. 46-15).

Between 10:09 a.m. and 10:15 a.m., Dr. Omar Kahn entered five orders for Allen. Among them was an order timed at 10:15 a.m. for a bolus and continuous infusion of heparin. (Doc. 46-4 at 2-3; Doc. 46-16).

Earlier, at 8:19 a.m., Nurse Christine Smith had, responding to a different order, obtained a 5000-units/ML, 1 ML vial of heparin. (Doc. 46-13, 8:19:34; Doc. 46-4 at 2). Thus, Nurse Smith

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[2] At age twenty, Allen was diagnosed with an atrial septal defect. (Doc. 41-1 at 1). He had it surgically repaired. (*Id.*).

already had on hand a 5,000-units/ML, 1 ML vial of heparin when she received the 10:15 a.m. order. (Doc. 46-4 at 3; Doc. 46-1 at 3).

Nurse Smith testified that she would have administered the heparin as soon as it was available, and that if it was already available, she could have administered the bolus in five minutes or less, as long as she was not interrupted. (Doc. 46-4 at 3; Doc. 46-1 at 3; Doc. 46-18 at 48:12-49:5).

Typical nursing practice is to administer a medication and then document the administration in the medical records. (Doc. 46-4 at 3). Nurse Smith testified that this was also her standard practice. (Doc. 46-18 at 17:15-18:20). She testified that she would have given the bolus dose of heparin and then later recorded that fact in the electronic Medication Administration Record. (Doc. 46-18 at 18:14-20). To make this recording, she would have had to return to the nursing station to access a computer terminal. (Doc. 46-4 at 3; Doc. 46-1 at 4; Doc. 46-18 at 18:14-20).

At 10:29 a.m., Allen's telemetry alarm sounded, and the monitor automatically saved the ECG strip reflecting the beginning of a cardiac event. (Doc. 46-4 at 4; Doc. 46-1 at 4; Doc. 46-20 at 3). The telemetry strip indicated a marked change in the ECG, as compared with prior readings. (*Id.*). Doctors performed an emergent ECG at 10:34 a.m. The 10:34 a.m. ECG indicated marked "ST elevations" and tachycardia (152 BPM). (Doc. 46-4 at 4; Doc. 46-1 at 5; Doc. 46-21 at 3).

Allen moved to the Cardiac Catheterization Lab (Cath Lab) at approximately 11:24 a.m. (Doc. 46-24 at 6). Doctors discovered multiple blood clots in Allen's arteries. (Doc. 46-1 at 5; Doc. 46-22 at 3-5; Doc. 46-24 at 3-28). He underwent a thrombectomy to extract clots from the left anterior descending coronary artery and the left posterior descending artery. (*Id.*).

Doctors in the Cath Lab administered an additional 20,000 units of heparin from two 1,000-units/ML, 10 ML vials at approximately 11:53 a.m. (Doc. 46-4 at 5; Doc. 46-13 at 3-4; Doc. 46-24 at 3).

Within eleven minutes of receiving these bolus doses, Allen became hypotensive and suffered cardiogenic shock. (Doc. 46- 4 at 5; Doc. 46-24 at 9-10; *see also* Doc. 46-22 at 3-5; Doc. 46-25 at 3-4). Allen's blood pressure fell to 103-over-83 by noon, and to 79-over-49 by 12:37 p.m. (*Id.*).

The Cath Lab operator also noted that Allen vomited blood after the cath procedure. (Doc. 46- 9 at 71:13-72:4). The exact timing of the vomiting is not documented, but Dr. Fortuin testified that Dr. Chapatell was in the room at 12:36 p.m., and that the only reason Dr. Fortuin would call her in is for an airway issue, such as vomiting. (Doc. 46-9 at 61:9-25).

Allen received intravenous vasopressors and an intra-aortic balloon pump in an attempt to reverse hypotension and improve cardiac function. (Doc. 46-1 at 5). Despite these measures, hypotension and cardiac failure persisted. (*Id.*).

The cardiogenic shock that Allen suffered in the Cath Lab resulted in renal failure. (Doc. 46-28 at 3-4).

Over the ensuing several days, Allen continued to demonstrate hemodynamic embarrassment with end organ failure, for which he required a total artificial heart. (Doc. 46-1 at 7).

Allen later developed Heparin Induced Thrombocytopenia. (Doc. 46-26 at 3-5; Doc. 46-27 at 3-5; *see also* Doc. 46-4 at 6; Doc. 46-1 at 7). Allen required further surgery to remove blood clots from the artificial heart. (Doc. 46-4 at 6).

On February 27, 2008, Allen underwent a heart transplant and kidney transplant, together with removal of the artificial heart. (Doc. 46-31 at 3-5). The transplanted heart failed, followed by multiple procedures, culminating in the final surgical intervention for Allen on March 7, 2008, during which he died. (Doc. 46-32 at 3).

In March 2008, the FDA announced that the active ingredient in some batches of Baxter Healthcare Corporation's (Baxter) heparin was contaminated with over-sulfated chondroitin sulfate ("OSCS"), a synthetic compound. (Doc. 1 at 4-5). OSCS is a known cardiac toxin. (Doc. 46-1 at 6). Studies have shown a link between OSCS and various adverse reactions suffered by heparin users. (Doc. 46 ¶ 6).

Plaintiff brought this action on February 9, 2010. (Doc. 1). She alleges that all of the heparin Allen received at Mayo on December 2, 2007 was contaminated Baxter heparin. (*Id.*). She asserts the contaminated heparin caused the various health problems that led to Allen's death. (*Id.*).

Hundreds of other plaintiffs across the country brought similar claims. The Judicial Panel on Multi-District Litigation established and sent the MDL to me.

Following extensive *Daubert* hearings, I held that only those individuals who had experienced one or more of the agreed-on contaminated heparin related symptoms *within sixty minutes of receiving the contaminated heparin* would be able to establish causation and survive summary judgment. *In re Heparin Prods. Liab. Litig.*, 803 F. Supp. 2d 712. In addition, I held that the plaintiff has the burden of proof of showing that the contaminated heparin came from Baxter and not another supplier. *Id.*

The pending summary judgment motion raises both issues. (Docs. 40, 41).

Standard of Review

Summary judgment is appropriate under Fed. R. Civ. P. 56 where the opposing party fails to show the existence of an essential element for which the party bears the burden of proof. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). The movant must initially show the absence of a genuine issue of material fact. *Id.* at 323.

Once the movant meets that initial burden, the "burden shifts to the nonmoving party [to] set forth specific facts showing there is a genuine issue for trial." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986). Rule 56 "requires the nonmoving party to go beyond the [unverified] pleadings" and submit admissible evidence supporting its position. *Celotex*, 477 U.S. at 324.

I accept the non-movant's evidence as true and construe all evidence in its favor. *Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 456 (1992).

Discussion

As noted, Baxter's summary judgment motion raises two issues: 1) whether Plaintiff has satisfied her burden of showing that Allen received contaminated Baxter heparin; and 2) whether Allen suffered any adverse effects attributable to contaminated heparin within sixty minutes of its administration. I address each issue in turn.

1. Product Identification

Allen received a total of four heparin doses during the morning of December 2, 2007. The approximate times and dosages were: 1) 6:00 a.m. (5,000-units/ML, 1ML vial); 2) 10:15 a.m. (5,000-units/ML, 1 ML vial); 3) 11:52 a.m. (1,000-units/ML, 10 ML vial); and 4) 11:53 a.m. (1,000-units/ML, 10 ML vial).

To prevail, plaintiff must, *inter alia*, identify one or more of the doses Allen received as Baxter heparin. *See, e.g.*, *Glaser v. Thompson Med. Co.*, 32 F.3d 969, 971 (6th Cir. 1994) (product identification plaintiff's burden); *In re Dow Corning Corp.*, 250 B.R. 298, 353-54 (Bankr. E.D. Mich. 2000) ("It is well established that product identification is an essential element of every products liability action, regardless of which state's law governs."); *Becton v. Starbucks Corp.*, 491 F. Supp. 2d 737, 749 (S.D. Ohio 2007) (plaintiff "has not been able to identify the designer or manufacturer of the [defective product], and has not been able to identify the serial numbers, model numbers, or lot numbers").[3]

To that end, plaintiff offers the affidavit of Patricia Earl, a pharmaceutical products expert. Earl opines as follows:

> In order to develop my opinions that Allen was administered adulterated Baxter heparin at Mayo, I traced the heparin that Allen received back from the hospital to the pharmaceutical wholesaler and then back to the manufacturer. To accomplish this, I reviewed all shipments of heparin from Baxter to Cardinal Health Phoenix ("Cardinal") and then all shipments of heparin from Cardinal to Mayo. Based on the Cardinal purchase orders, I was able to track Baxter heparin shipments from Baxter to Cardinal by lot numbers. The Baxter FCA Strategy Plan . . . identified all OSCS affected products manufactured by Baxter. Based on this information, I know what lot numbers of Baxter heparin were adulterated with OSCS. Therefore, I am able to ascertain when and in what quantity Cardinal acquired OSCS adulterated Baxter heparin. Prior to January 2008, and up until May 2015, there was no law or governmental regulations in the U.S. (except Florida) which required wholesalers, like Cardinal, to track and record the lot numbers of pharmaceuticals they sold and shipped to their customers. *Therefore, I then matched the timeframe of shipments from Cardinal to Mayo and evaluated the*

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[3] To the extent Arizona courts have addressed the issues defendants raise in their motion, Arizona law applies. *See In re Unitsed Parcel Serv., Air-In Ground Mktg. And Sales Practices Litig.*, 580 Fed. Appx. 543, 544 (9th Cir. 2014).

> *purchase order lead time, order replenishment patterns and inventory stocking history of Cardinal and Mayo from January 1, 2007 until February, 2008. As a result of my professional analysis, based on my decades of experience in pharmaceutical distribution, I was able to determine to a reasonable degree of professional certainty what lot numbers of Baxter heparin were shipped from Cardinal to Mayo and when those shipments occurred.*

(Doc. 46-3 ¶ 6) (emphasis added).

Based on that reasoning, Earl concludes 1) Baxter manufactured all of the heparin Allen received on December 2, 2007; and 2) all of that heparin was contaminated.

Earl's analysis is flawed.

The reliability of an expert's testimony "means that it must be 'supported by appropriate validation – i.e., "good grounds," based on what is known.'" *In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 530 (6th Cir. 2008) (citing *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 590 (1992)). Stated differently, reliability does not depend on the accuracy of the opinion but "whether it rests upon a reliable foundation, as opposed to, say, unsupported speculation." *Id.* at 529-30.

The allegation that all of the heparin Allen received was contaminated Baxter heparin "is not supported by reasonable inferences arising from the undisputed facts, but is based on speculation and conjecture that renders them mere guesses or possibilities." *Lee v. Celotex Corp.*, 764 F.2d 1489, 1491 (11th Cir. 1985); *see In re Darvocet, Darvon and Propoxyphene*, 856 F. Supp. 2d 904, 908 (E.D. Ken. 2012) (inferences supporting product identification must be reasonable). Earl makes several sweeping assumptions, unanchored in the record, that allow her to trace specific heparin lots from Baxter to Cardinal to Mayo to Allen, and to rule out the possibility that Allen received heparin

from another manufacturer.[4] Her chain of reasoning is simply too tenuous to support her conclusions. *See id.*

Indeed, Allen's own medical records contradict Earl. Mayo produced a document that lists, *inter alia*, the heparin amount, strength and vial size of each dose Allen received. (Doc. 41-3 at 24-25). Defendants argue that the twelfth column from the left in that document ("MedAltID") lists the National Drug Code ("NDC") number for the medication administered. When used to label medications, an NDC number takes the form, "#####-####-##." 21 C.F.R.§ 207.35. An NDC number identifies the manufacturer (the first set of digits), product (the middle set of digits), and package size (the last set of digits). *Id.*

The number listed in the MedAltID column for the 6:00 a.m. and 10:15 a.m. heparin administrations is "4691262." (*Id.*). Defendants cite two industry publications that list "00469-1262" as the manufacturer and product code assigned to heparin manufactured by APP Pharmaceuticals, LLC (APP), one of Baxter's main competitors. (Doc. 53-3 at 8).

On the other hand, the number listed in the MedAltID column for the 11:52 a.m. and 11:53 a.m heparin administrations is "00641-2440-41." Earl concedes that "00641" was the "manufacturer code for Baxter." (Doc. 53-3 at 869:21-870:6). Nonetheless, Earl testifies in her affidavit that the MedAltID number for the 6:00 a.m. and 10:15 a.m. administrations "likely was a Mayo internal reference number" and not an NDC number. (Doc. 46-2 ¶ 10). Earl thus implies it is mere coincidence that Mayo's "internal reference number" for certain Baxter heparin vials corresponded

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[4] For example, her analysis relies on, *inter alia*, educated guesses regarding the amount of time specific lots of heparin remained in Cardinal's, and then Mayo's, inventory. (Doc. 46-3 ¶ 6). Mere guesses do not establish a positive product identification. *Lee v. Celotex Corp.*, 764 F.2d at 1491; *In re Darvocet, Darvon and Propoxyphene*, 856 F. Supp. 2d at 908.

to the NDC number for APP heparin.[5]

No reasonable jury could reach that conclusion. "It strains credulity to think that the long arm of coincidence is so elastic as to reach to the extremes postulated by [plaintiff]. The law is not so struthious as to compel [me] to ignore the obvious." *U.S. v. Nocella*, 849 F.2d 33, 40 (1st Cir. 1988).

Accordingly, I find there is no genuine issue of material fact as to whether Baxter manufactured the heparin administered at 6:00 a.m. and 10:15 a.m; it clearly did not. There is, however, evidence sufficient to survive summary judgment that Baxter manufactured the heparin administered at 11:52 a.m. and 11:53 a.m; the NDC number for that heparin appears to identify Baxter as the manufacturer.

That said, Earl's product identification analysis may have an additional problem. Earl identifies four lots containing contaminated heparin in 1,000-units/ML 10ML doses that Baxter sold to Cardinal and that Cardinal allegedly sold to Mayo. Defendants, however, have submitted an exhibit indicating two of those lots were not contaminated.[6] (Doc. 53-3 at 23). It appears, then, that Earl cannot state with certainty that the Baxter heparin Allen received at 11:52 a.m. and 11:53 a.m. was contaminated.

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[5] I am not persuaded that the omission of the leading zeros or the internal hyphen means "4691262" is not the manufacturer and product code of an NDC number. Earl herself testified that "when you work with them everyday" (as no doubt the staff at Mayo did) you learn to identify NDC numbers written in shorthand. (Doc. 53-3 at 870).

[6] Plaintiff asks that I disregard that exhibit because it "has not been produced in discovery, it is not Bates numbered, it is not verified by an affidavit, and there is no indication as to who created the [exhibit] – or for what purpose." (Doc. 56 at 6). Because the parties have not fully briefed this evidentiary issue, and because I am denying defendants' motion anyway, I decline to decide it now. If plaintiff so chooses, she can challenge admissibility of the exhibit prior to trial. I note, however, that defendants submitted a duplicate of the original exhibit bearing a "BAX" Bates number which they say Baxter produced to MDL lead counsel. (Doc. 58-5).

But even if Earl is wrong, and she cannot point to direct evidence that those two lots were contaminated, that would not be fatal to plaintiff's claim. "Strict liability in tort has been adopted in Arizona as the rule in product liability cases." *Sionsky v. Phoenix Coca-Cola Bottling Co.*, 18 Ariz App. 10, 12 (1972). In such cases, a plaintiff may "use a *res ipsa loquitur* type of inference to prove the existence of a defect." *Cox v. May Dept. Store Co.*, 183 Ariz. 361, 364 n.2 (1995). Thus, plaintiff is "permitted to rely upon circumstantial evidence alone." *Dietz v. Waller* 141 Ariz. 107, 111 (1984) ("This would be especially true in cases such as this one where the product has disintegrated or burned up.").

As the Restatement (Third) of Torts: Products Liability § 3 (1998) explains:

> It may be inferred that the harm sustained by the plaintiff was caused by a product defect existing at the time of sale or distribution, without proof of a specific defect, when the incident that harmed the plaintiff:
>
> > a) was of a kind that ordinarily occurs as a result of a product defect; and
> >
> > b) was not, in the particular case, solely the result of causes other than product defect existing at the time and sale or distribution.

If plaintiff can prove any harm Allen suffered within sixty minutes after the 11:52 a.m. and 11:53 a.m. heparin administrations 1) was of a kind that normally occurs from contaminated heparin, and 2) Allen's health problems were, at least in part, due to receiving contaminated heparin, she will prevail.

Defendants emphasize that Allen had a history of heart problems and that he may already have been having a cardiac event before receiving Baxter heparin. Those facts are not relevant for the purposes of the instant motion. Arizona allows a jury to distinguish between predisposing

susceptibility and precipitating cause when determining liability. *Gasiorowski v. Hose*, 182 Ariz. 376 (1994); *see* Restatement (Third) of Torts: Products Liability, *supra*, § 16 (Increased Harm Due to Product Defect). A jury could find Baxter heparin made Allen's condition worse because it was contaminated, and impose liability on that basis. *See Doe v. Bayer Corp.*, 367 F. Supp. 2d 904, 913 (M.D.N.C. 2005) (recognizing separate claims for injury and enhancement of injury).

Of course, a jury could find that the 11:52 a.m. and 11:53 a.m. heparin doses did not contribute to Allen's health problems, in which case defendants would prevail.

In any event, there is a question of fact as to whether Allen received contaminated Baxter heparin at 11:52 a.m. and 11:53 a.m.

2. Timing of Adverse Reaction

Defendants also argue that plaintiff cannot prove that Allen had an adverse reaction within sixty minutes of receiving Baxter heparin. In light of the above analysis, *see, e.g.*, *Gasiorowski*, 182 Ariz. 376, that argument lacks merit.

Allen's medical records indicate that within eleven minutes of receiving the 11:52 a.m. and 11:53 a.m. heparin doses, Allen became hypotensive and suffered severe cardiogenic shock. Additionally, at least one witness testified that he believed Allen began vomiting blood within forty-five minutes of receiving the two doses. This evidence creates a jury question regarding the timing of any adverse reactions Allen may have suffered from Baxter heparin.

Conclusion

Because there are genuine issues of material fact as to plaintiff's claims, summary judgment is not warranted. This case will go to trial to determine whether Allen received Baxter heparin at

11:52 a.m. and/or 11:53 a.m. on December 2, 2007, and whether it caused him harm within sixty minutes of receiving it.

For the forgoing reason, it is hereby

ORDERED THAT defendant's motion for summary judgment (Docs. 40, 41) be, and the same hereby is, denied.

So ordered.

/s/ James G. Carr
Sr. U.S. District Judge